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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,212	06/07/2002	Atsushi Miyamoto	Q68293	4780
23373	7590	03/30/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,212

Applicant(s)

MIYAMOTO ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/3/02 2/17/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

1. Claims 1-10 are pending and currently under consideration.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Please see the cited references throughout the disclosure and pages 19-21.

3. The information disclosure statement (IDS) submitted on 1/30/02 and 2/17/05 have been considered as to the merits before First Action.

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. On page 4 , last paragraph, line 5 "tripsin" should be "trypsin". Appropriate correction is required.

5. The abstract of the disclosure is objected to because it contains more than one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 6 are vague and indefinite in reciting latex particles *carrying* an antibody or antigen because it is not clear if this claim language is intending to read on open language “comprising an antibody or antigen” or close language “consisting of an antibody or antigen”. It is suggested that the claim be re-written to replace carrying with the appropriate transitional phrase “comprising” or “consisting” to clarify the claims. Please correct.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Masson et al. (US Patent #4,427,781).

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Masson et al. teach a reagent comprising protease-treated albumin and antigen-coated particles. Digoxin BSA latex (latex conjugate) is mixed with pepsin treated samples to detect small haptens. See abstract and columns 5 and 6. The Digoxin BSA latex conjugate comprises bovine serum albumin (BSA - column 5 line 23), and Digoxin (antigen that specifically reacts with anti-digoxin - column 5 lines 29 and 46). This reagent is mixed with sample and pepsin and measured for agglutination. Once the mixtures are added they read on the two components recited in claim 6 (protease treated albumin as defined on page 5 and latex particles carrying an antigen).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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I. Claim 10 is rejected under 35 U.S.C.103(a) as being unpatentable over Masson et al. (US Patent #4,427,781) in view of Nakase et al. (JP 48019719 Abstract Only).

Please see Masson et al. as set forth above. Masson et al. disclose the reagent combination involving protease treatment in combination with BSA and antigen/antibody coated latex particles. However, Masson et al. do not teach the use of these reagents for anti-streptolysin O antibodies.

Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity. See abstract.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the protease treatment in combination with BSA and antigen/antibody coated latex particles detection reagents as taught by Masson et al. and utilize them in turbidity measurements for anti-streptolysin O antibodies/antigen assays because Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity. See abstract.

II. Claims 1-5 are rejected under 35 U.S.C.103(a) as being unpatentable over Kojima et al. (JP 07140145 Abstract Only) in view of Masson et al. (US Patent #4,427,781) and further in view of Nakase et al. (JP 48019719 Abstract Only).

Kojima et al. disclose turbidimetric assays for anti-streptolysin O antibodies. The assay of Kojima et al. utilizes an antigen-antibody complexes as well as a reducing agent and an agglutinating promoting agent to reduce non-specific binding thereby providing faster, simpler, and more accurate assay results. See abstract.

Kojima et al. differ from the instant invention in not specifically teaching BSA as the agglutinating promoting agent and pepsin as the reducing agent.

However, Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity (promoting agent). See abstract.

While, Masson et al. teach a reagent comprising protease-treated albumin and antigen-coated particles. Digoxin BSA latex (latex conjugate) is mixed with pepsin treated samples to detect small haptens. See abstract and columns 5 and 6. The Digoxin BSA latex conjugate comprises bovine serum albumin (BSA - column 5 line 23), and Digoxin (antigen that specifically reacts with anti-digoxin – column 5 lines 29 and 46). This reagent is mixed with sample and pepsin and measured for agglutination. Once the mixtures are added they read on the two components recited in claim 6 (protease treated albumin as defined on page 5 and latex particles carrying an antigen). Pepsin allows for the elimination of interfering proteins in agglutination procedures. See column 4 lines 45-49 and column 6 lines 10-13.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use BSA as taught by Nakase et al. and pepsin as taught by Masson et al. in the turbidimetric assays for anti-streptolysin O antibodies disclosed by Kojima et al. because Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity (see abstract) and Masson et al. disclosed that protease treatment eliminated protein interference in agglutination procedures (column 4 lines 45-49).

9. For reasons aforementioned, no claims are allowed.

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Remarks

10. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Masson et al. (EPO 0 061 857 A1) disclose pepsin digestion to eliminate protein interferences. See page 8 lines 25 through 30.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

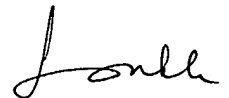
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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